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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/403,803	03/17/1995	RON S. ISRAELI	41426-A-PCT-	4181

7590 03/12/2003  
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EXAMINER

GUCKER, STEPHEN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/403,803

Applicant(s)

Israeli et al.

Examiner

Stephen Tucker

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 11/21/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1, 6, 13, 22-23, 34-35, 45, 47 is/are pending in the application. 49-52, 74-79, 100-105, & 113-126
- Of the above claim(s) 1, 6, 13, 22-23, 34-35, 45, 47, 49-52, 74-79 is/are withdrawn from consideration.
- ☒ Claim(s) 116-118 is/are allowed.
- ☒ Claim(s) 100-105, 113-115, & 119-126 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 26, 29, 34 & 36 ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

Office Action Summary

### **Part III DETAILED ACTION**

#### ***Response to Amendment***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. The disclosure is objected to because of the following informalities: on page 32, lines 2-4, and page 53, lines 25-26, describe the hydrophilicity of the predicted protein sequence as shown in Figure 16. Figure 16 does not describe hydrophilicity.

Appropriate correction is required.

4. Claims 113-115 and 119-126 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to these claims, filed 1/19/01, Paper No. 26, Amendment G, recites an outside region of prostate specific membrane antigen, the amino acid sequence of which outside region is set forth within SEQ ID NO:2 beginning with the amino acid number 45 at the amino terminus of the polypeptide. The Examiner can find no support for this outside region beginning with the amno acid number 45 at

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the amino terminus of the polypeptide in the regions of the specification where support for this amendment to the claims was identified by Applicant. This is a new matter rejection.

5. Claims 100-105, 113-115 and 121-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 100-105 and 121 are indefinite because they do not recite the specific hybridization conditions which Applicant regards as being specifically hybridizing to a nucleic acid sequence of SEQ ID NO:1. Whether or not specific hybridization occurs is a function of the hybridization conditions such as specific ionic strength, specific temperature, specific number of washings, etc. and therefore “hybridizes specifically” or “specifically hybridizes” as recited in the claims encompass a variety of conditions which will vary depending on the specific nucleotide sequence structures which are being claimed, i.e. length of sequences, G/C content of sequences, number and amount of competing or similar sequences in a particular sample, etc., and these claimed hybridizing sequences can only be adequately defined by specifically reciting hybridization conditions.

Claims 113-115 are confusing because it is unclear whether the Applicant is referring to the encoded polypeptides of the claimed nucleic acids or to the reference sequence of the outside region of prostate specific membrane antigen beginning with amino acid number 45 at the amino terminus when the claims use such phrases as “provided that the polypeptide [or fragment] is characterized by antigenicity” or “which polypeptide is characterized by antigenicity and comprises each of the following sequences...”. Basically, what polypeptide or fragment is being

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referred to in these claims, i.e. those encoded by the claimed nucleic acids or the outside region of prostate specific membrane antigen which is used as the framework to create the claimed nucleic acids?

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 100-102, 113-115, and 120-121 are rejected under 35 U.S.C. 102(a) as being anticipated by Sulavik et al. ("Sulavik"). Sulavik discloses GenBank sequence accession number M89776 (pages 3579 and 3582) whose nucleotides encode amino acids 60-67 of instant SEQ ID NO:2 (see attached sequence comparison). An eight amino acid peptide is of sufficient length to be antigenic and this entire sequence can selectively hybridize to SEQ ID NO:1 under very low stringency conditions since the conditions recited in the instant claims are not defined.

8. Claims 100-102, 113-115, and 120-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Palm et al. ("Palm"). Palm discloses the nucleotide sequence of virus SSV1 (pages 244-245) whose nucleotides encode amino acids 62-68 of instant SEQ ID NO:2 (see attached sequence comparison). A seven amino acid peptide is of sufficient length to be antigenic and this entire sequence can selectively hybridize to SEQ ID NO:1 under very low stringency conditions since the conditions recited in the instant claims are not defined.

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9. Claims 100-102, 113-115, and 120-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramakrishnan et al. ("Ramakrishnan"). Ramakrishnan discloses the nucleotide sequence of ribosomal protein L18 from *Bacillus stearothermophilus* (page 883) whose nucleotides encode amino acids 101-107 of instant SEQ ID NO:2 (see attached sequence comparison and enlarged page at end of this publication). A seven amino acid peptide is of sufficient length to be antigenic and this entire sequence can selectively hybridize to SEQ ID NO:1 under very low stringency conditions since the conditions recited in the instant claims are not defined.
10. Claims 116-118 are in condition for allowance.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

March 5, 2003

Gary L Kunz  
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